DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-148/S-025

Novo Nordisk, Inc.
Attention: Nina Liang, PhD
Manager, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

SUPPLEMENT APPROVAL

Dear Dr. Liang:

Please refer to your supplemental new drug application dated April 9, 2008, received April 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norditropin Cartridges (somatropin [rDNA origin] injection).

We acknowledge receipt of your submissions dated August 14, September 19, November 5 and 14, December 16, 2008, and March 4, 2009.

This supplemental new drug application provides for Norditropin NordiFlex (a prefilled, disposable, multi-dose Norditropin delivery device pen) in a 30 mg/3 mL strength presentation.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-148/S-025**."

CARTON AND IMMEDIATE CONTAINER LABELS, DEVICE LABELING

Submit final printed carton and container labels that are identical to the enclosed Norditropin Nordiflex 30 mg/3 mL carton and immediate container labels, Patient Information/Instructions for Use, NordiFlex PenMate carton and NordiFlex PenMate User Manual as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**Final Printed Carton and Container Labels for approved NDA 21-148/S-025**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane; Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We acknowledge your post-approval stability commitments where you will place the first three production batches of Norditropin NordiFlex 30 mg/3 mL on long term stability studies through the proposed expiration dating period **(b) (4)** and place at least one production batch of Norditropin NordiFlex 30 mg/3 mL per year on long term stability studies and report the results in the NDA annual report.

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert
Norditropin NordiFlex 30 mg/3 mL container label (submitted April 9, 2008)
Norditropin NordiFlex 30 mg/3 mL carton label (submitted April 9, 2008)
Norditropin NordiFlex 30 mg/3 mL PPI (submitted March 4, 2009)
-Patient Information
-Instructions for Use
NordiFlex PenMate carton (submitted March 4, 2009)
NordiFlex PenMate User Manual (submitted March 4, 2009)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks

3/10/2009 06:50:51 PM